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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/389,782	09/03/1999	COLIN R. DUNSTAN	A-604	5852
21069	7590	01/20/2004	EXAMINER	
AMGEN INCORPORATED MAIL STOP 27-4-A ONE AMGEN CENTER DRIVE THOUSAND OAKS, CA 91320-1799			HELMS, LARRY RONALD	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 01/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/389,782

Applicant(s)

DUNSTAN ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Claims 21-31 are pending.
Claims 21, 22, 23, 24, 26, 29, and 31 have been amended.
2. Claims 21-31 are under examination.
3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

Response to Arguments

4. The rejection of amended claim 21 under 35 U.S.C. 102(b) as being anticipated by Boyle et al (WO 97/23614, published 7/3/97, IDS #6) is maintained.

The response filed 10/23/03 has been carefully considered but is deemed not to be persuasive. The response of 10/23/03 states applicants have amended claim 21 to recite an OPG variant or fragment which has a deletion of one or more amino acids from positions 186-401 or has an amino acid sequence from 22-X wherein X is from 185-293 (see page 5 of response).

In response to this argument, The claim still encompasses OPG with 22-401 ^{4/24} because of the term "having" which is interpreted as open language which means an OPG protein with 22-X but it can also have more residues such as residues 22-401 which is taught by Boyle et al. Boyle et al clearly teach a fusion protein comprising an OPG variant 22-401 fused at its N-terminus to the C-terminus of the Fc protein (see

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page 105, lines 19-25) and it would be inherent that the protein has the activity of decreasing bone resorption.

5. The rejection of claims 21-31 under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (WO 97/23614, published 7/3/97, IDS #6) as applied to claim 21 and further in view of Mann et al (WO 98/28427, published 7/2/98, IDS #6) is maintained.

The response filed 10/23/03 has been carefully considered but is deemed not to be persuasive. The response of 10/23/03 states that the claimed FC-OPG fusion proteins are unexpected as one skill in the art could not have anticipated that addition of an Fc region to the amino terminus of an OPG polypeptide would enhance OPG activity of increasing bone density and applicants note that Boyle discloses truncations which have activity and this does not lead to the invention because the OPG peptides may be structurally or functionally different from ones that are truncated and conjugation of PEG to the N-terminus of OPG would not render obvious fusions of Fc-polypeptides to the N-terminus of OPG because these molecules would be structurally and functionally different (see page 5-6 of response). In response to this argument, Boyle et al teach FC-OPG (22-401) and as such it would obviously have the claimed properties of decreasing bone resorption because it is the same product as claimed. While Boyle does disclose truncations he discloses a molecule of Fc-OPG and these have OPG activity, therefore, it would have been obvious that one could produce a fusion protein with Fc-OPG or truncated versions thereof and in fact Boyle does. In addition, it would have been obvious to add PEG to the N-terminus because PEG-OPG and Fc-OPG

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have activity which suggests that proteins can be added to the N-terminus of the OPG and not alter activity.

Conclusions

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be

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reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879



LARRY R. HELMS, PH.D.
PRIMARY EXAMINER